

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N-0456]

RIN 0910-AF23

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Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to request comment on whether to amend certain provisions of the agency's nutrition labeling regulations concerning serving size. FDA is issuing this ANPRM as part of the agency's Obesity Working Group (OWG) food labeling recommendations to address the nation's obesity problem.

DATES: Submit written or electronic comments by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: You may submit comments, identified by Docket No. 2004N-0456 and/or RIN number 0910-AF23, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2004N-0456 and/or RIN number 0910-AF23 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori LeGault, Center for Food Safety and Applied Nutrition (HFS-840), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1791.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Serving Size Regulations

The Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) in section 403(q)(1)(A)(i) (21 U.S.C. 343(q)(1)(A)(i)) to require that most foods under FDA’s jurisdiction bear nutrition information based on a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure appropriate to the food. In accordance with the NLEA, FDA issued regulations establishing standards for defining serving sizes to be used on food labels (58 FR 2229, January 6, 1993) (the serving size final rule).

In the serving size final rule, we established Reference Amounts Customarily Consumed (Reference Amounts or RACCs), (upon which label serving sizes are to be determined) for 139 food product categories, including 11 categories for infant and toddler foods (§ 101.12(b)) (21 CFR 101.12(b)). The RACCs represent the amount of food customarily consumed per eating occasion for each product category, and were derived primarily from data obtained from the 1977–1978 and 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture (USDA) (58 FR 2229 at 2236–2237).

In deriving the RACCs, FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

We reviewed food consumption data for the foods in each product category and considered three statistical estimates, i.e., the mean (average), the median (50th percentile), and the mode (most frequent value). Following the

procedures detailed in the proposed rule that published in the **Federal Register** of November 27, 1991 (56 FR 60394 at 60403 through 60406), we determined the reference amount that was most likely to represent the amount customarily consumed for each product category.

We also established procedures for converting RACCs into appropriate label serving sizes as set forth in § 101.9(b). Among these provisions, in § 101.9(b)(6), we defined the criteria for products to be labeled as single-serving containers. (See 58 FR 2229 at 2232 through 2235 for FDA's evaluation of comments.) Most products packaged and sold individually that contain less than 200 percent of the applicable RACC must currently be labeled as a single serving. An exception to this rule occurs for products that contain between 150 percent and 200 percent of the RACC and that have a RACC of 100 grams (g) or 100 milliliters (mL) or larger, in which case, the product may be labeled as one or two servings, at the manufacturer's option. For products packaged and sold individually that contain 200 percent or more of the RACC, it is the manufacturer's option to label the product as a single-serving container if the entire content of the package can reasonably be consumed at a single-eating occasion.

B. The FDA Report of the Working Group on Obesity

On March 12, 2004, FDA released the agency's report of the Obesity Working Group (OWG) outlining an action plan to confront the nation's obesity problem (Ref. 1). The recommendations in the report are centered on the scientific fact that weight control is primarily a function of caloric balance and therefore focus on a "calories count" emphasis. One of the OWG's principal recommendations involves food labeling and, among other actions within this area, it charges the agency to determine which, if any, of the RACCs of food

categories appear to have changed significantly over the past decade and, therefore, would need to be updated.

The OWG report also charges the agency to reexamine its regulations on serving sizes. Furthermore, the OWG report noted that comments FDA had received at its public meetings and to the docket¹ expressed concern about the serving sizes used in nutrition labeling, particularly on packaged products that can readily be consumed at one eating occasion, but that indicate they represent more than one serving.

II. Agency Request for Information

A. Updating RACCs

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. Because there is evidence that the U.S. population is eating larger portion sizes than they did in the 1970s and 1980s (Ref. 1), the OWG recommends that FDA determine whether to update the RACCs, and if so, how to update the RACCs. Changes to the RACCs, in most instances, would require changes to the serving size on products, which in turn would require changes to the nutrient values listed on the nutrition label.

Newer food consumption data are available from the 1999–2000 and the 2001–2002 National Health and Nutrition Examination Surveys (NHANES) (Ref. 2), and they provide a more current indication of the amount of food being consumed by individuals. However, we do not want consumers to confuse the serving size on the food label (which is required by the act to

¹ During its tenure, the OWG met eight times. The OWG received briefings from several invited experts from other government agencies, held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups), and solicited comments on obesity-related issues, directing them to the docket established in July 2003 (Docket No. 2003N–0338).

be based on the amount customarily consumed) with the serving size provided in dietary guidance materials (which is based on recommended consumption amounts). For example, if data show that consumers are drinking larger amounts of soft drinks and FDA increases the RACC, which increases the serving size on the food label, educational efforts may be required to reinforce to consumers that a larger serving size on the container is not a “recommended” serving size.

We request comments on these issues and specifically on the following questions:

- Which, if any, RACCs of food categories appear to have changed the most over the past decade and therefore need to be updated?
- Should we use the most current data available from NHANES on food consumption to determine changes to the RACCs? Why or why not?
- What criteria should be used as the basis for changing RACCs? For example, would a percentage (e.g., 20 percent, 25 percent, or 30 percent) increase or decrease from current RACCs be a valid rationale for change?
- What research is available to show that consumers understand that serving sizes on food labels are not the same as serving sizes recommended in dietary guidance? What additional education efforts should be provided to consumers? Would consumers think that an increase in serving size on food labels means more of the food should be eaten?
- Would increasing the size of some of the RACCs be contrary to the goal of promoting consumption of smaller portion sizes, and hence of reducing obesity? Explain why or why not.

B. Single-Serving Containers

Several comments to the OWG docket strongly opposed the practice of individually packaged foods that appear to be single-serving containers, declaring two or more servings on the label—such as sodas and snack packs. In addition, as noted in the OWG report, FDA initiated eight focus groups around the country and, among other questions, asked consumers about serving size information on small packages. Examples of food labels were presented for a 20 fluid (fl) ounce (oz) soda and an individually packaged large muffin. In general, consumers thought that having multiple servings listed on the label for these products was misleading and confusing.

To address this issue, we ask for comments on the following questions:

- Should FDA initiate rulemaking to require packages that can reasonably be consumed at one eating occasion to provide the nutrition information for the entire package? If so, what specific types of products and package sizes can reasonably be consumed at one eating occasion and should be required to bear nutrition information for the entire package?
- What alternatives for product labeling should be required? For example, should such products be required to include an additional column within the Nutrition Facts panel to list the quantitative amounts and % Daily Value for the entire package, as well as the preexisting columns listing the quantitative amounts and % Daily Value for a serving that is less than the entire package? Alternatively, should the nutrition information only be declared for the entire package as a single serving?
- The current cutoff criteria for single serving containers (200 percent of the RACC (or 150 percent for products that have a RACC of 100 g or 100 mL or larger)) does not appear to be appropriate across the board for all food

categories. As previously noted, consumers in focus groups said they thought that having multiple servings listed on the label of a 20 fl oz soda (250 percent of the RACC) was misleading and confusing. How should the current cutoff criteria to define single-serving containers be changed? Should criteria vary for different types of products? Explain why or why not. What criteria should be used to designate which package sizes should be required to list nutrition information for the entire package? In addition to the three statistical estimates previously mentioned (namely, the mean, median, and mode), food consumption surveys allow calculation of intake estimates for individuals who eat a greater amount of food (e.g., those in the 90th and 95th percentiles). Should package sizes falling at these amounts (e.g., 90th or 95th percentile), as reported from nationwide food consumption surveys, be used as cut points at or below which nutrition information should be included for the entire package? If so, the RACC tables in § 101.12(b) would have to be modified to include a column for the amount specific to each product category as a cut point for when a product must be labeled as a single-serving container. Is this a viable option? If not, how can single-serving containers be defined?

C. Comparison of Calories in Foods of Different Portion Sizes

As noted in the OWG Report, the Federal Trade Commission has suggested that FDA consider “allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.” Our current regulations for comparative nutrient content claims, including calorie claims, require that all such comparisons be based on a uniform amount of food, i.e., per RACC for individual foods or per 100 g for meals and main dishes. Consequently, the current regulations (§ 101.60(b)) do not permit claims that compare the amount of calories in different sized portions of the same food.

Nevertheless, as noted in the OWG report, “using the food label to promote consumption of smaller portions may have merit [particularly] if consumers understand that (1) the calorie reduction is solely a function of the reduction in portion size and (2) the smaller portion size is actually less than what they usually consume.” Thus, we solicit comments regarding the appropriateness of label claims based on the amount of calories in a specified portion of a product (i.e., the amount of food specified by the claim, e.g., one cookie) vs. claims based on the labeled serving size of a product (i.e., the amount specified in the Nutrition Facts panel, e.g., two cookies). We ask for specific comments on the following questions:

- Because all currently approved comparative claims are based on the difference in the amount of the nutrient in a uniform amount of food such as per RACC, or per 100 g, will it be confusing to consumers to have claims made only on the basis of the difference in the amount of calories in two different labeled servings (i.e., the serving size specified in the Nutrition Facts panel, e.g., 8 oz vs. 12 oz cans of soda) or two different portions (i.e., amounts specified by the claim, e.g., one cookie vs. two cookies) of the same food? Explain why or why not.

- If a claim is made based only on the difference in the amount of calories in two different serving sizes or portions of the same food, what words should be used to ensure that consumers understand that comparisons are made only on this basis (i.e., the difference in the amount of product) and that there is not a difference based on product reformulation, e.g., “the caloric savings is based on a smaller than normal portion?”

- Should the size of the compared servings, portions, or packages be part of the claim (e.g., “this 8 fl oz bottle of juice has 33 percent fewer calories than our 12 fl oz bottle”)? Explain why or why not.
- Should these types of claims be limited to products that are identical except for the specified serving or portion size? Explain why or why not.
- Will such claims be misleading if the claim is based on the amount of calories that is in an amount of food other than what is specified in the Nutrition Facts panel? (e.g., claims based on half a “labeled serving” —one cookie, compared to the amount specified in the Nutrition Facts panel—two cookies)
- Should this claim be limited to single-serving containers, or is it appropriate on multi-serving packages? Explain why or why not.
- If claims are permitted on multi-serving packages, should these claims be limited to products that have portioned pieces, such as cookies or slices of bread, or should they be allowed on products that are not portion controlled, such as pies or bulk sodas? For example, might this claim be extended to “bulk” products such as pizza suggesting that if you cut a smaller slice, you will get a caloric savings?
- What comparative terms are appropriate? Because “reduced” has always been used to signal some type of reformulation (i.e., special processing, alteration, formulation, or reformulation to lower the nutrient content), is it appropriate to use the term “reduced” on products that have not been so altered? Is “less than,” which has been more broadly used to signal differences in nutrient levels derived through a variety of means, a more appropriate term?
- Currently all comparative calorie claims are limited to reductions of at least 25 percent. Should these comparisons (e.g., reduced or fewer calories)

continue to be limited to reductions of at least 25 percent, and if not, what justification is there that a smaller reduction of calories would be meaningful and significant? Please provide data.

- What other requirements may be necessary to ensure that the claim is not confusing or misleading to consumers?

III. Future Analysis of Benefits and Costs

To help us determine which regulatory options might solve the problems associated with consumer misunderstanding of serving sizes and for the agency's future analysis of benefits and costs associated with those options, we request comments, including available data, on the following questions:

- In the 2002 Health and Diet Survey (Ref. 3), respondents were asked how they used the Nutrition Facts panel. Following are the most common answers: (1) To see if the product was high or low in a specific nutrient, (2) to decide how much to eat, and (3) to help in meal planning. How do serving sizes contribute to these uses? What changes in serving sizes or reference amounts would make food labels more useful to consumers?
- Participants in focus groups have asked for serving sizes that represent amounts that they would be likely to consume. What are reasons for and against realistic serving sizes? What do consumers currently think the serving sizes on packaged foods represent? For example, do they regard the serving size as a recommendation of how much to eat?
- If the nutrient amount per serving size (derived from the RACC) and per package were listed side-by-side in separate columns, how would this affect consumers' ability to understand the label? What should the serving size be on products like a 20 fl oz soda or a large muffin? What criteria should FDA use to determine which multi-serving products should have per package

labeling? Should it be based on the total amount in the container, the type of food, or something else?

- If manufacturers can make truthful and nonmisleading label comparisons of different portion sizes of foods, what is the likely change in the distribution of package sizes that will become available to consumers? What other labeling changes would encourage a broader range of package sizes?

- Larger packages have been identified as a possible cause of overeating. Larger packages also typically sell for less per unit than smaller packages. What government regulatory options would lead to manufacturers offering smaller packages?

- What do consumers think are the differences between serving sizes on food labels and serving sizes recommended in dietary guidance? What information on a label would help make this distinction clearer?

- How can the number of servings per container be made more prominent?
- The information on serving size on the food label is scientifically-based, but does not include any recommendations. Should the agency consider adding recommendations to the food label? If so, what recommendations should be added? For example, should the position of the food within the USDA Food Guide Pyramid (Ref. 4) be indicated on the label?

- If there are specified package sizes below which manufacturers must list the nutrient content of the entire package, are manufacturers likely to repackage products in larger sizes to avoid this requirement? If so, what are the likely impacts of this repackaging?

- Describe some alternative, simpler ways to help consumers determine their nutrient intake based on what they eat? What are the advantages and disadvantages of these options?

- Are you aware of any research, consumer or industry-based, that can assist the agency in this matter?

If the agency proposes regulatory changes based on the initiatives outlined in this ANPRM, we will estimate the costs of labeling changes and other potential costs (such as the costs of reformulating products) should the regulations create incentives for new products. The comments on this ANPRM may identify other costs as well. The benefits of the regulatory options depend on how consumers respond to the changes in label serving sizes or portion sizes. We will use the information from comments to help determine ways to estimate the possible consumer responses to various changes. The comments will also contribute to our estimates of the effects of regulatory options on small entities.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses but is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Report of the Working Group on Obesity, "Calories Count" (Internet address: <http://www.cfsan.fda.gov/~dms/owg-toc.html>), March 12, 2004.
2. U.S. Department of Health and Human Services, National Center for Health Statistics, NHANES 1999–2000 Data Files (Internet address: http://www.cdc.gov/nchs/about/major/nhanes/NHANES99_00.htm) and NHANES 2001–2002 Data Files (Internet address: <http://www.cdc.gov/nchs/about/major/nhanes/nhanes01-02.htm>).
3. Food and Drug Administration, Center for Food Safety and Applied Nutrition, "2002 Health and Diet Survey—Preliminary Topline Frequencies (Weighted)," March 2004.

4. U.S. Department of Agriculture, Center for Nutrition Policy and Promotion, The Food Guide Pyramid, Washington, DC, Home and Garden Bulletin No. 252, (Internet addresses: <http://www.usda.gov/cnpp/pyrabklt.pdf> or http://www.pueblo.gsa.gov/cic_text/food/food-pyramid/main.htm), 1996.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed

comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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